

50. A method of detecting a target polynucleotide indicative of breast cancer in a test sample comprising:

(a) contacting the test sample with at least one diagnostic polynucleotide selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, and complements thereof;

(b) detecting a presence of the target polynucleotide indicative of breast cancer in the test sample.

*original claim
not directed
to b/c*

51. A method of detecting a target polynucleotide indicative of breast cancer in a test sample comprising:

(a) contacting the test sample with at least one diagnostic polynucleotide comprising position 1-357 of SEQ ID NO:4 and complements thereof;

(b) detecting the target polynucleotide indicative of breast cancer in the test sample.

52. A method of detecting a target polynucleotide indicative of breast cancer in a test sample comprising:

(a) contacting the test sample with at least one diagnostic polynucleotide comprising position SEQ ID NO:5 and complements thereof;

(b) detecting the target polynucleotide indicative of breast cancer in the test sample.

*broaden
b/c no*

53. A method for detecting mRNA of a target polynucleotide indicative of breast cancer in a test sample, said method comprising:

(a) performing reverse transcription on said sample using at least one primer in order to produce cDNA;

(b) amplifying the cDNA obtained from step (a) to obtain an amplicon, said amplifying using sense and antisense primers wherein each primer comprises at least 10

nucleotides corresponding to a polynucleotide selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, and complements thereof; and

(c) detecting a presence of the amplicon in the test sample, wherein the presence of the amplicon indicates detection of the target polynucleotide indicative of breast cancer in the test sample.

54. A method for detecting mRNA of a target polynucleotide indicative of breast cancer in a test sample, said method comprising:

(a) performing reverse transcription on said sample using at least one primer in order to produce cDNA;

(b) amplifying the cDNA obtained from step (a) to obtain an amplicon, said amplifying using sense and antisense primers wherein each primer comprises at least 10 nucleotides corresponding to positions 1-357 of SEQ ID NO:4 and complements thereof; and

(c) detecting a presence of the amplicon in the test sample, wherein the presence of the amplicon indicates detection of the target polynucleotide indicative of breast cancer in the test sample.

55. A method for detecting mRNA of a target polynucleotide indicative of breast cancer in a test sample, said method comprising:

(a) performing reverse transcription on said sample using at least one primer in order to produce cDNA;

(b) amplifying the cDNA obtained from step (a) to obtain an amplicon, said amplifying using sense and antisense primers wherein each primer comprises at least 10 nucleotides corresponding to SEQ ID NO:5 and complements thereof; and

(c) detecting a presence of the amplicon in the test sample, wherein the presence of the amplicon indicates detection of the target polynucleotide indicative of breast cancer in the test sample.

56. The method of claim 53, wherein the test sample is reacted with a solid phase prior to performing one of steps (a), (b) or (c).

57. The method of claim 53, wherein said detecting step comprises utilizing a detectable label capable of generating a measurable signal.

58. A method of detecting a target polynucleotide indicative of breast cancer in a test sample suspected of containing said target polynucleotide, comprising:

(a) contacting the test sample with at least one sense primer and with at least one anti-sense primer wherein each primer comprises at least 10 nucleotides corresponding to a polynucleotide selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2 and complements thereof; and amplifying to obtain a first stage reaction product;

(b) contacting said first stage reaction product with at least one oligonucleotide probe to obtain a second stage reaction product, with the proviso that the oligonucleotide probe is (i) located 3' to the primers utilized in step (a) and (ii) is complementary to said first stage reaction product, wherein the probe comprises at least 10 contiguous nucleotides corresponding to a polynucleotide selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2 and complements thereof; and

(c) detecting said second stage reaction product as an indication of a presence of the target polynucleotide indicative of breast cancer in the test sample.

59. A method of detecting a target polynucleotide indicative of breast cancer in a test sample suspected of containing said target polynucleotide, comprising:

(a) contacting the test sample with at least one sense primer and with at least one anti-sense primer wherein each primer comprises at least 10 nucleotides corresponding to position 1-357 of SEQ ID NO:4 and complements thereof; and amplifying to obtain a first stage reaction product;

(b) contacting said first stage reaction product with at least one oligonucleotide probe to obtain a second stage reaction product, with the proviso that the oligonucleotide probe is (i) located 3' to the primers utilized in step (a) and (ii) is complementary to said first stage reaction product, wherein the probe comprises at least 10 contiguous nucleotides corresponding to position 1-357 of SEQ ID NO:4 and complements thereof; and

(c) detecting said second stage reaction product as an indication of a presence of the target polynucleotide indicative of breast cancer in the test sample.

60. A method of detecting a target polynucleotide indicative of breast cancer in a test sample suspected of containing said target polynucleotide, comprising:

(a) contacting the test sample with at least one sense primer and with at least one anti-sense primer wherein each primer comprises at least 10 nucleotides corresponding to SEQ ID NO:5 and complements thereof; and amplifying to obtain a first stage reaction product;

(b) contacting said first stage reaction product with at least one oligonucleotide probe to obtain a second stage reaction product, with the proviso that the oligonucleotide probe is (i) located 3' to the primers utilized in step (a) and (ii) is complementary to said first stage reaction product, wherein the probe comprises at least 10 contiguous nucleotides corresponding to SEQ ID NO:5 and complements thereof; and

(c) detecting said second stage reaction product as an indication of a presence of the target polynucleotide indicative of breast cancer in the test sample.

61. The method of claim 58, wherein the test sample is reacted with a solid phase prior to performing one of steps (a), (b) or (c).

62. The method of claim 58, wherein said detecting step comprises utilizing a detectable label capable of generating a measurable signal.

63. The method of claim 62, wherein said detectable label is reacted with a solid phase.

64. A test kit useful for detecting a target polynucleotide indicative of breast cancer in a test sample, comprising:

a container containing at least one polynucleotide selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2 and complements thereof.

65. A test kit useful for detecting a target polynucleotide indicative of breast cancer in a test sample, comprising:

a container containing at least one polynucleotide comprising position 1-357 of SEQ ID NO:4 and complements thereof.

66. A test kit useful for detecting a target polynucleotide indicative of breast cancer in a test sample, comprising:

a container containing at least one polynucleotide comprising SEQ ID NO:5 and complements thereof.

67. A purified polynucleotide selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, and complements thereof.

68. A purified polynucleotide comprising position 1-357 of SEQ ID NO:4 and complements thereof.

69. A purified polynucleotide comprising SEQ ID NO:5 and complements thereof.

70. The purified polynucleotide of claim 67 wherein said polynucleotide is produced by recombinant techniques.

71. The purified polynucleotide of claim 67 wherein said polynucleotide is produced by synthetic techniques.

72. The purified polynucleotide of claim 67 wherein said polynucleotide comprises a sequence encoding at least one epitope.

73. A recombinant expression system comprising:
a nucleic acid sequence that includes an open reading frame operably linked to a control sequence compatible with a desired host, wherein said nucleic acid sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2 and complements thereof.

74. A recombinant expression system comprising:
a nucleic acid sequence that includes an open reading frame operably linked to a control sequence compatible with a desired host, wherein said nucleic acid sequence comprises position 1-357 of SEQ ID NO:4 and complements thereof.

75. A recombinant expression system comprising:
a nucleic acid sequence that includes an open reading frame operably linked to a control sequence compatible with a desired host, wherein said nucleic acid sequence comprises SEQ ID NO:5 and complements thereof.

76. A cell transfected with the recombinant expression system of claim 73.

77. A cell transfected with a nucleic acid sequence encoding at least one epitope, wherein said nucleic acid sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, and complements thereof.

78. A cell transfected with a nucleic acid sequence encoding at least one epitope, wherein said nucleic acid sequence comprises position 1-357 of SEQ ID NO:4 and complements thereof.

79. A cell transfected with a nucleic acid sequence encoding at least one epitope, wherein said nucleic acid sequence comprises SEQ ID NO:5 complements thereof.

80. A composition of matter comprising a polynucleotide, the polynucleotide selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2 and complements thereof.

81. A composition of matter comprising a polynucleotide, the polynucleotide comprising position 1-357 of SEQ ID NO:4 and complements thereof.

82. A composition of matter comprising a polynucleotide, the polynucleotide comprising SEQ ID NO:5 and complements thereof.

83. The test kit of claim 64 further comprising:
a container with tools useful for collection of said sample, wherein the tools are selected from the group consisting of lancets, absorbent paper, cloth, swabs and cups.

84. An isolated DNA molecule comprising SEQ ID NO:22.

protein
onkluin

REMARKS

The Examiner states that the parent application U.S. Application Serial No. 08/879,345 filed June 1997 does not disclose the specific fragments as set forth in the Amendment. Applicant respectfully disagrees.